

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY**

DUKE UNIVERSITY, ALLERGAN, INC., and  
ALLERGAN SALES, LLC,

Plaintiffs and Counterclaim  
Defendants,

v.

AKORN, INC. and HI-TECH PHARMACAL  
CO., INC.,

Defendants and Counterclaim  
Plaintiffs.

Civil Action No. 3:18-CV-14035

**ORAL ARGUMENT REQUESTED**

*Electronically Filed*

**PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION  
TO DISMISS AKORN'S ANTITRUST AND PATENT MISUSE COUNTERCLAIMS  
AND TO STRIKE RELATED AFFIRMATIVE DEFENSES, OR ALTERNATIVELY,  
TO BIFURCATE AND STAY AKORN'S ANTITRUST AND PATENT MISUSE  
COUNTERCLAIMS AND RELATED AFFIRMATIVE DEFENSES**

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### **PRELIMINARY STATEMENT**

Akorn has employed the all too common litigation tactic of accused infringers trying to use the antitrust laws to collaterally attack the patents that they are accused of infringing. Stripped of its rhetoric, the heart of Akorn’s antitrust and patent misuse counterclaims is that Plaintiffs’ current and prior patent infringement lawsuits were allegedly a “sham,” aimed at harming Akorn and allegedly preventing competition with Plaintiffs’ branded eyelash hair-growth drug product LATISSE®. Akorn’s allegations are not only insufficient to state a claim as a matter of U.S. antitrust law, but they amount to a belated attempt to re-litigate unsuccessful motions for attorneys’ fees under U.S. patent law that Akorn raised or could have raised long ago.

First and foremost, Akorn’s counterclaims fail because innovators like Duke and Allergan are awarded legal monopolies by the U.S. Patent and Trademark Office (“USPTO”). Once a patent issues, the First Amendment protects the patentee’s right to enforce that patent free of antitrust scrutiny, subject only to two narrow exceptions. The sole exception that Akorn relies upon is “sham litigation” under Section 2 of the Sherman Act, 15 U.S.C. § 2. To state a claim for sham litigation, Akorn has the heavy pleading burden of alleging facts showing, among other things, that Plaintiffs’ patent infringement lawsuits were “objectively baseless” at the time they were filed—*i.e.*, without any probable cause. *See Prof’l Real Estate Inv’rs, Inc. v. Columbia Pictures Indus., Inc. (“PRE”),* 508 U.S. 49, 60–61 (1993).

Akorn fails to include any factual allegations whatsoever in support of its conclusory claims that three of Plaintiffs’ prior patent infringement lawsuits against Akorn amount to sham litigation. In any event, none of Plaintiffs’ four patent infringement lawsuits against Akorn comes close to meeting the exacting Supreme Court test for “objectively baseless” litigation.

- *Latisse I-IV*: All of Plaintiffs’ lawsuits were brought pursuant to the Hatch-Waxman Act, which mandates the quick filing of patent infringement actions.

- *Latisse I*: The first lawsuit was an extremely hard-fought case that ***Plaintiffs won in the district court***, with the Federal Circuit reversing in a divided 2-1 ruling.
- *Latisse II*: Akorn's co-defendant sought attorneys' fees at the conclusion of the patent case, arguing that the second lawsuit was "objectively baseless." The district court rejected this argument and denied the request. There was no appeal.
- *Latisse III*: Akorn itself sought attorneys' fees arguing that the third patent lawsuit was "objectively baseless." The district court again rejected the motion, concluding that the infringement action was ***not frivolous***. Akorn did not appeal and should be collaterally estopped from claiming this lawsuit was "objectively baseless" under U.S. antitrust law when it lost the identical argument under a lower standard in patent law.
- *Latisse IV*: The current lawsuit is based upon a recently issued patent, which is presumed valid and conforms to Federal Circuit guidance in the first lawsuit.

For all of these reasons, Akorn has not—and cannot—plausibly allege that ***any patent lawsuit*** rises to the level of "sham," and Akorn's antitrust and patent misuse counterclaims should be dismissed. The Court should in turn strike Akorn's identical and insufficiently pled affirmative defenses.

Alternatively, if the Court is not inclined to dismiss Akorn's antitrust and patent misuse counterclaims at this time, these counterclaims and related affirmative defenses should be stayed pending resolution of the current patent infringement lawsuit. First, these counterclaims could be eliminated entirely if Plaintiffs succeed on their infringement claim. Second, injecting these antitrust counterclaims into the patent case would greatly expand the scope of discovery and implicate complex, fact-intensive antitrust issues completely unrelated to the patent infringement lawsuit, including, for example, all of the reasons for Akorn's four-year delay in securing FDA approval. In addition, these counterclaims could lead to jury confusion and even bias against Plaintiffs, prejudicing a fair trial of their patent infringement claim. For all of these reasons, numerous courts have recognized that bifurcating antitrust and unrelated patent counterclaims has long been the "standard practice," *In re Innotron Diagnostics*, 800 F.2d 1077, 1084–85 (Fed. Cir. 1986), along with stays of separate discovery. At a minimum, the same result is warranted here.

Accordingly, Plaintiffs respectfully request that the Court dismiss Akorn's antitrust and

patent misuse counterclaims (Counts IV-VIII) in their entirety and strike the identical affirmative defenses (Seventh, Eighth, and Ninth) or, alternatively, stay these counterclaims and defenses pending the outcome of Plaintiffs' underlying patent infringement action.

## **BACKGROUND**<sup>1</sup>

### **I. THE PATENTS AT ISSUE**

Allergan, Inc., the corporate parent of Allergan Sales, LLC (together, "Allergan"), is the holder of approved New Drug Application No. 22-369 for LATISSE<sup>®</sup> (bimatoprost ophthalmic solution, 0.03%).<sup>2</sup> Dkt. 1 ("Compl.") ¶ 35. On February 28, 2017, the USPTO issued U.S. Patent No. 9,579,270 ("’270 patent"), titled "Compositions and Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins," to Duke University ("Duke"). *Id.* at ¶ 18-19. Claims 22 and 30 of the ’270 patent cover methods of using LATISSE<sup>®</sup>. *Id.* at ¶ 40. Allergan is the exclusive licensee of the ’270 patent-in-suit. *Id.* at ¶ 20.

Pursuant to a December 18, 2007, License Agreement between Duke and Allergan (collectively, "Plaintiffs"), Allergan has the right to "prosecute at its own expense any infringement of the Patent Rights." Dkt. 8-2, § 8-02(b). Allergan can "request to use the name of Duke as party plaintiff," and "[i]f Duke is a necessary party to an infringement lawsuit," then Duke

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<sup>1</sup> This section contains information from judicial filings in the patent proceedings and documents attached to or incorporated by reference into the pleadings. It is well-settled in this Circuit that "[i]n evaluating a motion to dismiss, [courts] may consider documents that are attached to or submitted with the complaint, and any matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders, and items appearing in the record of the case." *Buck v. Hampton Twp. Sch. Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (citation and internal quotation marks omitted); *Crisdon v. City of Camden*, No. 11-02087, 2012 WL 685874, at \*2 (D.N.J. Mar. 2, 2012) (same); *see also Benihana of Tokyo, Inc. v. Benihana Inc.*, No. 10-1051, 2011 WL 3861897, at \*2 n.1 (D. Del. Sept. 1, 2011) (considering a document that was submitted to the USPTO and publicly available on a motion to dismiss).

<sup>2</sup> LATISSE<sup>®</sup> is indicated to treat hypotrichosis of the eyelashes by increasing their growth, including, length, thickness, and darkness.

will join. *Id.* at § 8.02(b). Additionally, if Allergan does not bring a lawsuit against an infringing party within three months of discovery, then “Duke shall have the right . . . to prosecute at its own expense any such infringements.” *Id.* at § 8.04.

Plaintiffs and Hi-Tech Pharmacal Co., Inc., along with its parent company, Akorn, Inc., (collectively, “Akorn”) have previously litigated other patents that cover LATISSE<sup>®</sup>, including U.S. Patent No. 7,388,029 (“’029 patent”). The asserted ’270 patent claims priority to the application that led to the ’029 patent. Compl. ¶ 41. Allergan and Akorn also previously litigated the following patents owned by Allergan that cover LATISSE<sup>®</sup>: Patent Nos. 7,351,404 (“’404 patent”); 8,038,988 (“’988 patent”); 8,101,161 (“’161 patent”); 8,263,054 (“’054 patent”); and 8,926,953 (“’953 patent”).

## II. THE CURRENT AND PRIOR PATENT INFRINGEMENT LAWSUITS

### A. *Latisse I*

In August 2011, Plaintiffs sued Hi-Tech<sup>3</sup> (and other co-defendants) in the Middle District of North Carolina (“M.D.N.C.”) for patent infringement of the ’029 and ’404 patents after Hi-Tech filed its Abbreviated New Drug Application (“ANDA”) No. 203051. *Allergan, Inc. et al. v. Hi-Tech Pharmacal Co.*, No. 1:11-cv-650 (M.D.N.C.), Dkt. 1 (“*Latisse I*”). Hi-Tech sought to make and sell a generic version of LATISSE<sup>®</sup> by filing an ANDA with the Food and Drug Administration (“FDA”), as allowed by the Hatch-Waxman Act, 21 U.S.C. § 355(j). *Allergan, Inc. v. Apotex Inc.*, No. 10-681, 2013 WL 286251, at \*1 (M.D.N.C. Jan. 24, 2013), *rev’d in part*, 754 F.3d 952 (Fed. Cir. 2014). Hi-Tech provided notice to Plaintiffs of its “paragraph IV certification,” which alleged that the ’029 and ’404 patents are “invalid or will not be infringed by” Hi-Tech’s generic drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Filing an ANDA seeking

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<sup>3</sup> Akorn admits that Akorn acquired Hi-Tech in April 2014, Dkt.8 (“Ans. and Counterclaims”), at ¶ 6, which occurred after the district court issued its initial decision in *Latisse I*.

approval for a drug, the use of which is claimed in a patent, is an act of infringement under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2), which prompted Plaintiffs to file suit. *Allergan*, 2013 WL 286251, at \*1.

Following extensive briefing, discovery, and an eight-day bench trial, the M.D.N.C. issued a 25-page opinion in Plaintiffs' favor in January 2013. *Latisse I*, Dkt. 95, at 25. The M.D.N.C. concluded that Plaintiffs "met their burden to prove, by a preponderance of the evidence, that Defendants' ANDA products infringe . . . the '029 Patent and . . . the '404 Patent under the Court's construction. Defendants have not proven, by clear and convincing evidence, that the '029 and '404 patents are invalid." *Allergan*, 2013 WL 286251, at \*13. Hi-Tech appealed, and in June 2014, the Federal Circuit, in a 2-1 decision, reversed-in-part the M.D.N.C., finding the asserted claims of the '029 and '404 patents invalid as obvious. *Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 970 (Fed. Cir. 2014). The dissenting judge, however, concluded "that the district court did not clearly err in holding the asserted claims of the '029 patent nonobvious." *Id.* at 974 (Chen, J., dissenting).

## **B. *Latisse II*<sup>4</sup>**

While *Latisse I* was pending in the M.D.N.C., Allergan obtained three new patents, the '988, '161, and '054 patents, with claims covering methods of using LATISSE®. *Allergan, Inc. v. Hi-Tech Pharmacal Co.*, No. 1:12-cv-00492 (M.D.N.C.), Dkt. 1; *Allergan, Inc. v. Apotex Inc.*, 1:13-cv-00016 (M.D.N.C.), Dkt. 1 ("*Latisse II*"). Allergan filed two lawsuits (consolidated into *Latisse II*) asserting these new patents and alleging that Hi-Tech (and other co-defendants) infringed them. *Id.* The M.D.N.C. had not yet decided *Latisse I* at this time.

Shortly after the M.D.N.C. ruled in favor of Plaintiffs in *Latisse I* and Hi-Tech appealed,

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<sup>4</sup> Duke University was not a party to *Latisse II*.

Hi-Tech sought and obtained a stay of *Latisse II* pending the appeal in *Latisse I*. *Latisse II*, No. 1:12-cv-00492, Dkt. 39. The divided Federal Circuit panel then reversed the M.D.N.C.’s finding of patent validity in *Latisse I*. *Allergan*, 754 F.3d at 970. The parties then agreed to dismiss *Latisse II*, and the M.D.N.C. granted dismissal. *Latisse II*, No. 1:12-cv-00247, Dkts. 106, 115. Notably, Hi-Tech’s co-defendant (Apotex Inc.) moved for judgment on the pleadings, arguing that Allergan was collaterally estopped from asserting or contesting validity in *Latisse II*, and at the same time sought attorneys’ fees, arguing that the case was objectively baseless and thus “exceptional” under 35 U.S.C. § 285 (“Section 285”). Hochstadt Decl., Exs. A, B, *Allergan, Inc. v. Apotex Inc.*, No. 1:12-cv-00247 (M.D.N.C. Oct. 27, 2014), Dkts. 103, 104. The district court found collateral estoppel but denied the request for fees, concluding the case was “not exceptional.” Hochstadt Decl., Ex. C, *Allergan, Inc. v. Apotex Inc.*, No. 1:12-cv-00247 (M.D.N.C. Oct. 21, 2015), Dkt. 114.

### **C. *Latisse III***

On December 9, 2014, the USPTO issued U.S. Patent No. 8,906,962 (“’962 patent”), which also covered methods of using LATISSE®. *Allergan, Inc. v. Sandoz, Inc. et. al*, No. 1:14-cv-1034 (M.D.N.C.), Dkt. 1 (“*Latisse III*”). Allergan and Duke then brought a patent infringement action against Akorn. *Id.* In January 2015, the USPTO issued the ’953 patent, and Allergan added it to the *Latisse III* complaint. *Latisse III*, Dkt. 15. The ’962 patent, and Duke, were thereafter dropped from the suit. *Latisse III*, Dkt. 47.

The M.D.N.C. held that Allergan was collaterally estopped from asserting or contesting validity of the ’953 patent based upon *Latisse I* and *II*. *Latisse III*, Dkt. 72. The Federal Circuit affirmed as to the asserted claims. *Allergan, Inc. v. Sandoz, Inc.*, 681 F. App’x 955, 960–61 (Fed. Cir. 2017). Akorn then moved for attorneys’ fees, arguing that Allergan’s claims were objectively baseless and thus “exceptional” under Section 285. *See* Hochstadt Decl., Exs. D, E, *Latisse III*, Dkts. 84, 85. The district court again rejected this argument, concluding that Allergan’s lawsuit

“was not frivolous” and that it was “not satisfied by a preponderance of the evidence that Allergan’s conduct was exceptional.” Hochstadt Decl., Ex. F, *Latisse III*, Dkt. 97. Akorn did not appeal the M.D.N.C.’s decision.

**D. *Latisse IV***

In February 2017, the USPTO issued the ’270 patent, which also covers methods of using LATISSE®. Compl. ¶¶ 18, 64. The ’270 patent claims priority to the application that led to the ’029 patent invalidated in *Latisse I*, but the asserted claims of the ’270 patent are limited significantly compared to the ’029 patent. *Id.* at ¶ 50. In *Latisse I*, the Federal Circuit found the ’029 patent claims obvious in part because they covered a wide range of prostaglandin compounds not limited to amides at the C-1 position. *See id.* at ¶ 48. In contrast, the asserted claims of the ’270 patent are limited to prostaglandin compounds with an amide at the C-1 position, which the M.D.N.C. found, and the Federal Circuit agreed, behaved differently than and produced unexpected results as compared to prior art prostaglandin compounds. *Id.* at ¶¶ 47, 49–50.

On July 13, 2018, Akorn provided notice to Plaintiffs of its “paragraph IV certification.” Compl. ¶ 51. In response, Plaintiffs filed this lawsuit (“*Latisse IV*”) on September 19, 2018, asserting that Akorn’s efforts to gain FDA approval for and ultimately market a generic copy of LATISSE® infringed Claims 22 and 30 of the ’270 patent. *See generally* Compl. On November 19, 2018, Akorn responded with a number of antitrust and patent Counterclaims, mostly predicated on allegations that Plaintiffs engaged in sham litigation by filing *Latisse I-IV*. Dkt. 8 (“Ans. and Counterclaims”). Akorn brings four separate antitrust counts and a related patent misuse count, alleging actual monopolization based upon the filing of *Latisse IV* and *Latisse I-IV* cumulatively (Counts IV and V), attempted monopolization (Count VI), conspiracy to monopolize (Count VII), and patent misuse (Count VIII), seeking treble damages, declaratory relief, and attorneys’ fees and



expenses. *Id.* (collectively, the “Antitrust and Misuse Counterclaims”). Additionally, Akorn asserts nearly identical affirmative defenses, arguing that Plaintiffs’ enforcement of the current patent-in-suit constitutes patent misuse (Seventh Affirmative Defense), sham litigation (Eighth Affirmative Defense), and conspiracy in restraint of trade (Ninth Affirmative Defense). *Id.* at 24 (collectively, the “Antitrust and Misuse Defenses”).

### **STATEMENT OF ISSUES AND LEGAL STANDARDS**

The Court must determine whether Akorn’s Antitrust and Misuse Counterclaims should be dismissed under Federal Rule of Civil Procedure (“Rule”) 12(b)(6) for failing to plausibly allege that Plaintiffs filed any “objectively baseless” patent infringement lawsuits involving LATISSE<sup>®</sup> against Akorn reaching the level of “sham” litigation. Under Rule 12(b)(6), a party must allege “enough facts to state a claim to relief that is plausible on its face,” and “factual allegations must be enough to raise a right to relief above the speculative level.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 570 (2007). Mere “labels and conclusions” or “a formulaic recitation of the elements of a cause of action will not do.” *Id.* at 555.

Relatedly, the Court must determine whether to strike Akorn’s identical Seventh, Eighth, and Ninth affirmative defenses (patent misuse, sham litigation, and antitrust conspiracy) under Rule 12(f) as facially insufficient, redundant, and lacking any factual support. Under Rule 12(f), a “court may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” Fed. R. Civ. P. 12(f). A “court is not required to accept affirmative defenses that are mere ‘bare-bones conclusory allegations,’ and may strike such inadequately pleaded defenses.” *Sonos, Inc. v. D&M Holdings, Inc.*, No. 14-1330, 2016 WL 4249493, at \*2 (D. Del. Aug. 10, 2016) (citations omitted), *adopted by*, 2016 WL 4581078 (D. Del. Sept. 1, 2016). Moreover, “[m]otions to strike ‘serve a useful purpose by eliminating insufficient defenses and saving the time and expense which would otherwise be spent litigating

issues which would not affect the outcome of the case.”” *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 WL 2804953, at \*4 (D.N.J. June 28, 2017) (quoting *United States v. Kramer*, 757 F. Supp. 397, 410 (D.N.J. 1991)).

In the alternative, the Court must decide whether to bifurcate and stay discovery of Akorn’s Antitrust and Misuse Counterclaims and Defenses pending the outcome of Plaintiffs’ patent infringement lawsuit since the resolution of this lawsuit may eliminate these counterclaims as a matter of law. Under Rule 42(b), courts have the authority to order a separate trial of any counterclaim “[f]or convenience, to avoid prejudice, or to expedite and economize.” It is also well-settled that this court has the inherent authority to control its own docket, and the decision to bifurcate claims and stay discovery is within the district court’s sole discretion. *See Landis v. N. Am. Co.*, 299 U.S. 248, 254–55 (1936).

### **MOTION TO DISMISS ARGUMENT**

#### **III. COUNTS IV-VI: AKORN FAILS TO PLAUSIBLY ALLEGE SHAM LITIGATION OR A SERIES OF ALLEGED SHAM LITIGATIONS**

##### **A. Akorn Cannot Meet the High Pleading Burden to Strip Plaintiffs of Their *Noerr-Pennington* Immunity**

Akorn has not satisfied its high burden to plead that this case is a sham, or that Plaintiffs filed a series of sham litigations. Plaintiffs, like all patent owners, have the lawful right to enforce patents and to exclude competitors. Under the “*Noerr-Pennington* doctrine,” the First Amendment shields conduct petitioning the government, including the courts, from antitrust liability. *See, e.g., In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 147 (3d Cir. 2017) (“A plaintiff claiming that a lawsuit is, by its very existence, anticompetitive and unlawful faces an uphill battle.”).

To strip a party filing a patent infringement lawsuit of *Noerr-Pennington* immunity, Akorn must ultimately show, at a minimum, that a lawsuit was objectively baseless *at the time of filing*.

*PRE*, 508 U.S. at 60–61. Even if a lawsuit is ultimately unsuccessful, “a court must ‘resist the understandable temptation to engage in *post hoc* reasoning by concluding’ that an ultimately unsuccessful ‘action must have been unreasonable or without foundation.’” *Id.* at 60 n.5. Courts must evaluate the lawsuit “in light of . . . information [available] at the time of filing.” *Rohm & Haas Co. v. Brotech Corp.*, 127 F.3d 1089, 1093 (Fed. Cir. 1997). Because Akorn does not—and cannot—plausibly allege that any lawsuit filed by Plaintiffs was objectively baseless at the time of filing, Akorn’s sham litigation claims fail as a matter of law.

i. Akorn Does Not Even Allege that *Latisse I-III* Were Sham Litigations

First and foremost, Akorn fails to plead any factual allegations in support of its conclusory claims that *Latisse I-III* were sham litigations. Akorn’s allegations with respect to *Latisse I-III* consist only of the following conclusory assertions: Plaintiffs’ lawsuits were (1) “made, not out of a genuine interest in redressing grievances, but as part of a pattern or practice of successive filings undertaken for purposes of harassment;” (2) “brought as part of an anticompetitive scheme;” and (3) “not legitimate petitioning of the Court.” Ans. and Counterclaims ¶ 174. Akorn alleges no facts at all in support of its claims,<sup>5</sup> and such a “formulaic recitation of the elements” falls far short under *Twombly*. 550 U.S. at 555. The Court should dismiss Akorn’s series of sham litigations claims with respect to *Latisse I-III* on this basis alone.

ii. Plaintiffs Had a Reasonable Basis to File All *Latisse* Lawsuits

Next, even assuming that Akorn pled that *Latisse I-III* were objectively baseless (which it did not), Akorn’s claims still fail because Plaintiffs had a reasonable basis to file each and every

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<sup>5</sup> In fact, Akorn appears to exclude *Latisse I* from the claimed series of sham lawsuits, alleging that Plaintiffs only became “aware that the asserted claims of several patents were invalid as obvious “[f]ollowing *Latisse I*.” *Id.* at ¶ 175 (emphasis added).

lawsuit.<sup>6</sup> Issued patents are presumptively valid, and “that presumption takes away any need for a plaintiff to prove his patent is valid to bring a claim.” *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1929 (2015). In fact, “it will be a rare case in which a patentee’s assertion of its patent in the face of a claim of invalidity will be so unreasonable as to support a claim that the patentee has engaged in sham litigation.” *Tyco Healthcare Grp. LP v. Mut. Pharm. Co.*, 762 F.3d 1338, 1345 (Fed. Cir. 2014).

Moreover, Plaintiffs’ patent infringement “actions were consistent with the design and intent of Hatch-Waxman.” *Wellbutrin*, 868 F.3d at 157. The Third Circuit has recognized that “[t]he already high hurdle for stating an antitrust claim for anticompetitive litigation is higher still in the context of an ANDA case[.]” *Id.* at 149 (citation omitted). Plaintiffs filed *Latisse I-IV* in response to Akorn’s ANDA filings containing paragraph IV certifications, which automatically qualify as acts of infringement. *See, e.g., AstraZeneca AB v. Mylan Labs., Inc.*, No. 00-6749, 2010 WL 2079722, at \*4 (S.D.N.Y. May 19, 2010) (“[A]t the outset. . . , Mylan gave Astra an objectively reasonable basis to sue: Mylan provided Astra notice of its Paragraph IV certification.”), *aff’d*, 412 F. App’x 297 (Fed. Cir. 2011); *Wellbutrin*, 868 F.3d at 149 (“The sham litigation claim . . . fails for the simple reason that an act of infringement plainly occurred.”). Plaintiffs were “objectively reasonable in acting on that technical act of infringement, and that alone provides a sufficient basis” for filing *Latisse I-IV*. *Id.* Any alleged “litigiousness [is thus] a

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<sup>6</sup> Plaintiffs could not assert the patents in *Latisse I-IV* in a single action due to the timing of their issuances from the USPTO. Plaintiffs filed *Latisse I* in August 2011 in response to paragraph IV certifications. The USPTO issued three new patents the next year (while *Latisse I* was pending), and Allergan asserted these new patents in *Latisse II* in March 2012 and January 2013. The USPTO issued another patent in December 2014, which Allergan asserted in *Latisse III* later that month. As for *Latisse IV*, the USPTO issued that patent in February 2017, and Plaintiffs filed this current action in September 2018 in response to Akorn’s paragraph IV certification in July 2018. Ans. and Counterclaims ¶ 55.

product of Hatch-Waxman”—not Plaintiffs. *Kaiser Found. Health Plan, Inc. v. Abbott Labs, Inc.*, 552 F.3d 1033, 1047 (9th Cir. 2009).

Additionally, any allegations that each individual *Latisse* lawsuit was objectively baseless are implausible as well for the specific reasons outlined below.

iii. Plaintiffs Won in the District Court in *Latisse I*

*Latisse I* cannot be objectively baseless because Plaintiffs **succeeded on the merits** in the M.D.N.C.—“an important factor to be considered under the sham inquiry.” *Boulware v. State of Nevada, Dep’t of Human Res.*, 960 F.2d 793, 798 (9th Cir. 1992). Conspicuously absent from Akorn’s recount of the facts in its Answer and Counterclaims is **any** mention of the M.D.N.C.’s trial court decision in Plaintiffs’ favor, finding the patents valid and that Akorn infringed them. That factor alone should render implausible any allegation that *Latisse I* was a sham.

At worst, *Latisse I* was a “hard-fought and close” litigation. *AstraZeneca*, 2010 WL 2079722, at \*4. Courts routinely hold that non-frivolous lawsuits cannot give rise to liability even if unsuccessful or if the patents are ultimately found invalid. *See, e.g., id.* (granting 12(b)(6) dismissal in Hatch-Waxman context: “This court may not infer automatically that Astra’s infringement action against Mylan was objectively baseless just because Astra lost at trial.”); *In re Lantus Direct Purchaser Antitrust Litig.*, 284 F. Supp. 3d 91, 110 (D. Mass. 2018) (same: “The fact that *Sanofi I* was litigated so extensively before settlement is evidence that the claims involved were not baseless.”), *appeal filed*, No. 18-2086 (1st Cir. Nov. 2, 2018).<sup>7</sup> Here, after extensive

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<sup>7</sup> *See also Ervin Equip. Inc. v. Wabash Nat’l Corp.*, No. 15-104, 2017 WL 416304, at \*3 (N.D. Ind. Jan. 31, 2017) (granting 12(b)(6) dismissal: “While I dismissed two of the three claims in the original complaint and denied the motion for preliminary injunction, those rulings were not slam dunks.”); *cf. Syncsort Inc. v. Innovative Routines Int’l Inc.*, No. 04-3623, 2008 WL 1925304, at \*18 (D.N.J. Apr. 30, 2008) (“That this Court is not granting summary judgment . . . on all of Syncsort’s claims demonstrates that Syncsort had a reasonable belief that there was a chance that its claims would be upheld upon adjudication.”); *Dominant Semiconductors Sdn. Bhd. v. OSRAM GmbH*, 524 F.3d 1254, 1261–64 (Fed. Cir. 2008) (finding infringement-related communications

litigation on appeal, the Federal Circuit ultimately reversed the M.D.N.C.’s validity holding, but even the Federal Circuit’s decision was not clear-cut. The Federal Circuit issued a detailed twenty-two page opinion, with one judge dissenting because he “would find that the district court did not clearly err in holding the asserted claims of the ’029 patent nonobvious.” *Allergan*, 754 F.3d at 974 (Chen, J., dissenting). Given that the M.D.N.C. judge and at least one Federal Circuit judge found in Plaintiffs’ favor, Akorn cannot plausibly argue that Plaintiffs *unreasonably believed* they “had some chance of winning” when they filed suit. *PRE*, 508 U.S. at 65. This extensive, hard-fought “outcome hardly bespeaks baseless litigation.” *AstraZeneca*, 2010 WL 2079722, at \*4.

iv. The District Court Rejected the Argument that *Latisse II* Was Objectively Baseless

Next, Akorn has not alleged—and cannot allege—that *Latisse II* was objectively baseless. Allergan filed *Latisse II* while *Latisse I* was pending in the M.D.N.C., and “the essential question is not whether the suit succeeds, but whether the suit was a sham *at the time it was filed*.” *Wellbutrin*, 868 F.3d at 148 (emphasis added). None of Plaintiffs’ patents had been declared invalid when *Latisse II* was filed, and even so, there is no “need for a plaintiff to prove his patent is valid to bring a claim.” *Commil*, 135 S. Ct. at 1929. Allergan reasonably filed *Latisse II* based upon Akorn’s technical infringement after the USPTO issued its patents. The parties ultimately agreed to dismiss the case and were ordered to bear their own costs.

Additionally, the M.D.N.C. recognized that *Latisse II* was not objectively baseless when it concluded that it was not “exceptional” and denied attorneys’ fees under Section 285. Section 285 allows “[t]he court in exceptional cases [to] award reasonable attorney fees to the prevailing party.” Akorn’s co-defendant filed such a motion explicitly arguing that Allergan’s claims were allegedly

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were not objectively baseless even where an ALJ found infringement in ITC action for only one of ten patents); *Q-Pharma, Inc. v. Andrew Jergens Co.*, 360 F.3d 1295, 1304-05 (Fed. Cir. 2004) (finding infringement claim was not objectively baseless even though voluntarily dismissed).

“contrary to law, *objectively baseless*, and *frivolous*.” Hochstadt Decl., Ex. A, at 3 (emphasis added); *see also* Hochstadt Decl., Ex. B, at 19 (“Allergan’s claims in Latisse® II . . . are *objectively baseless*.”) (emphasis added).

The M.D.N.C. rejected this argument, refusing to award attorneys’ fees for an exceptional case. Hochstadt Decl., Ex. C, at 3. And the “exceptional case” standard under Section 285 is *lower* than the sham litigation standard that applies here. In *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, the Supreme Court considered whether the standards were the same given that “meritless claims” could be exceptional, but found the *PRE* sham litigation test “too restrictive.” 572 U.S. 545, 555 (2014). Because the district court already found *Latisse II* not objectively baseless under this lower standard, it cannot be objectively baseless under the more exacting *PRE* standard. *See Shuffle Tech Int’l LLC v. Sci. Games Corp.*, No. 15-3702, 2017 WL 3838096, at \*7 (N.D. Ill. Sept. 1, 2017) (finding that the judge’s denial of attorneys’ fees under Section 285 “ruled on a key issue relevant to plaintiffs’ theory of sham litigation: whether the suit . . . was objectively baseless”). The M.D.N.C.’s ruling renders it implausible that *Latisse II* was a sham.

v. The District Court Found That *Latisse III* Was Not Objectively Baseless, and Akorn Is Collaterally Estopped from Re-litigating This Issue

In *Latisse III*, Akorn itself moved for attorneys’ fees against Allergan, arguing extensively that Allergan’s lawsuit was objectively baseless and thus exceptional under Section 285. Hochstadt Decl., Exs. D, E. The M.D.N.C. **rejected Akorn’s argument**, again refusing to award attorneys’ fees. Hochstadt Decl., Ex. F. Because the district court already found that *Latisse III* was not objectively baseless (as it did in *Latisse II*), this suit also cannot plausibly amount to sham.

Moreover, Akorn should be collaterally estopped from re-litigating the same argument that *Latisse III* was a sham. Collateral estoppel applies in the Third Circuit when: “(1) the identical issue was previously adjudicated; (2) the issue was actually litigated; (3) the previous

determination was necessary to the decision; and (4) the party being precluded from relitigating the issue was fully represented in the prior action.” *Jean Alexander Cosmetics, Inc. v. L’Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006).

In *Latisse III*, the M.D.N.C.’s denial of Akorn’s “motion for fees conclusively decided an issue that is *identical* to a necessary element of [Akorn’s] claim for sham litigation”—whether it was objectively baseless. *Shuffle Tech*, 2017 WL 3838096, at \*6 (emphasis added). Akorn extensively litigated this fact, arguing: (1) “There was *no objective basis* for Allergan to believe it had any chance of succeeding;” (2) “Allergan [pursued] *objectively baseless litigation* of the ’953 patent claims;” (3) “Allergan’s attempts in this litigation . . . were facially irrational and *objectively unreasonable*;” (4) “Allergan . . . caused Akorn to . . . defend itself against these *baseless* claims;” and (5) “Allergan continued its futile, protracted litigation campaign against Akorn, regardless of the *objective baselessness* of its arguments.” Hochstadt Decl., Ex. E, at 2–3, 6, 10 (emphasis added).

After consideration, the M.D.N.C. issued a final judgment, rejecting Akorn’s argument. Hochstadt Decl., Ex. F. This determination was essential to the judgment because it addressed precisely the argument that Akorn proffered in support of why the case was exceptional under Section 285. The M.D.N.C. succinctly summarized Akorn’s argument before rejecting it: “They assert that because this Court and the Federal Circuit invalidated substantively identical claims in a previous lawsuit, Allergan had *no objective basis* to believe it could succeed with the ’953 lawsuit.” *Id.* at 1 (emphasis added). The M.D.N.C. then concluded, “Allergan’s position in this lawsuit . . . *was not frivolous*”—*i.e.*, not objectively baseless. *Id.* at 4 (emphasis added). Whether Allergan brought an objectively baseless lawsuit in *Latisse III* was thus “precisely the argument that [the M.D.N.C.] *considered and rejected* when evaluating [Akorn’s] motion for attorneys’



fees.” *Shuffle Tech*, 2017 WL 3838096, at \*6 (emphasis added). Collateral estoppel should bar Akorn from re-litigating this identical argument from *Latisse III*.

vi. *Latisse IV* Has Yet to Be Adjudicated and Has Objective Merit

As for *Latisse IV*, Plaintiffs’ lawsuit is not only objectively reasonable, but pending. If Plaintiffs prevail, Akorn’s sham litigation claim fails as a matter of law. *See PRE*, 508 U.S. at 60 n.5. Even if the case is hard-fought but unsuccessful, the result is the same. *See supra* Section I.A.iii. Moreover, Plaintiffs are reasonable in enforcing this patent, which is again presumed valid, given that the ’270 patent fixes the flaws the Federal Circuit found with the broader ’029 patent claims invalidated in *Latisse I*. *See* Compl. at ¶ 49-50. Akorn fails to meet this pleading burden.

**B. The “Series Test” Does Not Apply to Plaintiffs’ Lawsuits**

As discussed above in Section I.A.i, Akorn fails to even allege a series of sham litigations. Akorn provides no factual allegations whatsoever in support of whether *Latisse I-III* were shams, and it is not even clear from Akorn’s pleading which lawsuits are supposedly included in the alleged series. Akorn’s factual allegations focus entirely on the current lawsuit, *see* Ans. and Counterclaims ¶¶ 132–149, 156–158, 176, which is pending and cannot plausibly amount to a “series” of sham litigations.

However, even if Akorn plausibly alleged that *Latisse I-IV* were sham litigations (and it did not), the result should be the same. When considering a large “series of legal proceedings,” the Third Circuit has at times applied a more flexible but similar approach to determine if a significant number of the lawsuits were objectively baseless—the so-called “series test.” *See Hanover 3201 Realty, LLC v. Vill. Supermarkets, Inc.*, 806 F.3d 162, 179–80 (3d Cir. 2015) (“[T]he question is not whether any one [lawsuit] has merit . . . but whether they are brought pursuant to a policy of starting legal proceedings without regard to the merits and for the purpose of injuring a market rival.”). The series test, however, should not apply here.

First, Plaintiffs filed suit according to the Hatch-Waxman Act. The Third Circuit has never applied the series test in this context, recognizing that “[t]he serial petitioning charge is particularly inapt because [these] actions [are] consistent with the design and intent of Hatch-Waxman.” *Wellbutrin*, 868 F.3d at 157. The Third Circuit further explained that it is “not inclined to penalize a brand-name manufacturer whose ‘litigiousness was a product of Hatch-Waxman’” because “[d]oing so would punish behavior that Congress sought to encourage.” *Id.* at 158 (citation omitted). The Court should decline to penalize Plaintiffs for the same conduct here.

Additionally, the number of lawsuits at issue is too few to qualify as a “series.” Courts, including the Federal Circuit, have refused to apply the series test to such a small number of lawsuits. *See, e.g., ERBE Elektromedizin GmbH v. Canady Tech. LLC*, 629 F.3d 1278, 1291–92 (Fed. Cir. 2010) (applying *PRE* to three lawsuits because they “are not ‘simultaneous and voluminous’ and do not implicate a test for ‘a whole series of legal proceedings’”).<sup>8</sup> And the Third Circuit acknowledged in *Hanover* that even four lawsuits are not necessarily enough to qualify as a series. 806 F.3d at 181 (“[W]e do not... find that four sham petitions will always support the use of [the series test].”). This Court should accordingly apply the *PRE* test to the *Latisse* actions.

But regardless of whether the series test applies, Akorn fails to plausibly allege sham litigation. Under the series test, the Third Circuit examines “win-loss percentage,” and there can be no sham “[i]f more than an insignificant number of filings have objective merit.” *Hanover*, 806

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<sup>8</sup> *See also Polaris Indus. v. Arctic Cat, Inc.*, No. 15-4475, 2017 WL 1180426, at \*6 (D. Minn. Mar. 29, 2017) (“[T]hree cases is not enough to constitute a series of legal proceedings to establish a practice of reprehensible or illegal anticompetitive behavior.”); *Rubloff Dev. Grp., Inc. v. Supervalu, Inc.*, No. 10-3917, 2013 WL 441152, at \*3 (N.D. Ill. Feb. 5, 2013) (“This Court . . . does not find the three lawsuits . . . to be a whole series of legal proceedings for the purposes of the ‘pattern’ exception.”). As for Duke, it was only involved in two prior *Latisse* litigations, which undoubtedly cannot qualify as a “series.” *See, e.g., Amarel v. Connell*, 102 F.3d 1494, 1519 (9th Cir. 1996) (“[P]laintiffs cite only two lawsuits, not a ‘series’ or a ‘pattern’ of them.”).

F.3d at 181. Thus, the series test at its core assesses whether the infringement lawsuits have *objective* merit. And if a litigant wins or could reasonably believe that it “ha[s] some chance of winning,” then a lawsuit (or multiple lawsuits) has objective merit. *PRE*, 508 U.S. at 65. As detailed above, not one of the *Latisse I-IV* litigations was objectively baseless, so Akorn’s sham litigation counterclaims fail under the series test as well.

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In sum, given (1) the presumption of validity for Plaintiffs’ patents, (2) the design and intent of the Hatch-Waxman Act which encourages the prompt filing of patent infringement suits, (3) Plaintiffs’ initial success in *Latisse I*, (4) the timing of the filings, (5) the M.D.N.C.’s refusal to award attorneys’ fees for objectively baseless litigation in *Latisse II* and *Latisse III*, and (6) the pending status of *Latisse IV* based upon a newly issued patent that conforms to Federal Circuit guidance, Akorn cannot plausibly allege that any of the lawsuits—let alone a significant number of them—were objectively baseless. Akorn’s monopolization and attempted monopolization claims based upon sham litigation (Counts IV-VI) should be dismissed.

#### IV. AKORN’S OTHER COUNTERCLAIMS FAIL FOR MULTIPLE REASONS

##### A. Count VII: Akorn Fails to Convert an Ordinary Patent License Term Into an Unlawful Conspiracy to Monopolize Claim

A conspiracy is “a conscious commitment to a common scheme *designed to achieve an unlawful objective*.” *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 760–64 (1984) (emphasis added). Here, Akorn challenges a typical term in an exclusive licensing contract regarding who controls third-party litigation, alleging that it amounts to “an explicit and implicit conspiracy.” Ans. and Counterclaims ¶ 209. Under the licensing agreement between Allergan and Duke, Allergan can bring patent infringement lawsuits, or alternatively, Duke can bring a lawsuit if Allergan does not do so. Ans. and Counterclaims, Ex. 2 §§ 8.02, 8.04. Rather than

evidencing any unlawful scheme, Plaintiffs' licensing agreement is entirely "in line with a wide swath of rational and competitive business strategy." *Twombly*, 550 U.S. at 554. That is precisely why courts refuse to infer a conspiracy from challenges to ordinary commercial behavior.<sup>9</sup> Akorn's conspiracy allegations thus fail to "nudge[] [its] claims across the line from conceivable to plausible," *Twombly*, 550 U.S. at 570, and the Court should dismiss the claim.

Additionally, Akorn fails to allege a conspiracy "because of the relationship between [Duke] and [Allergan], an exclusive licensee and patent holder." *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 2174499, at \*5 (D. Del. May 26, 2011). Courts, including in this Circuit, have found such a licensor and licensee incapable of conspiring under U.S. antitrust law. *See, e.g., id.* ("[D]istrict courts have held that other parties with unified interests, **such as a patent holder and licensee**, are incapable of conspiring.") (emphasis added); *Levi Case Co. v. ATS Prods., Inc.*, 788 F. Supp. 428, 431–32 (N.D. Cal. 1992) (holding that a patent owner and its exclusive licensee could not conspire as a matter of law). In fact, while Akorn challenges Plaintiffs' licensing term as a "conspiracy," courts hold that "[a]s a general rule, 'a patent owner should be joined, either voluntarily or involuntarily, in any patent infringement suit brought by an exclusive licensee having fewer than all substantial patent rights.'" *Shionogi*, 2011 WL 2174499, at \*5 (quoting *Amgen, Inc. v. Ariad Pharm., Inc.*, 513 F. Supp. 2d 34, 41 (D. Del. 2007)). Such a licensing term is thus not only typical, but recommended. Akorn's claim should be dismissed on this basis also.

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<sup>9</sup> *See, e.g., In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 321 (3d Cir. 2010) (quoting *Matsushita Elec. Indus., Co. v. Zenith Radio Corp.*, 475 U.S. 574, 594 (1986)) (cautioning against inferences regarding ordinary business behavior because it may "chill the very conduct the antitrust laws are designed to protect"); *Bristow Endeavor Healthcare, LLC v. Blue Cross & Blue Shield Ass'n*, 691 F. App'x 515, 519 (10th Cir. 2017) (dismissing antitrust conspiracy claims: "An inference of conspiracy is impermissible if the defendants'...conduct is consistent with other, equally plausible explanations."); *Kendall v. Visa U.S.A., Inc.*, 518 F.3d 1042, 1048–49 (9th Cir. 2008) (same: "[A]ccount of [] defendant's commercial efforts stays in neutral territory.").

Finally, Akorn simply tries to repackage its sham litigation arguments into a conspiracy claim. For all of the reasons stated above as to why Akorn fails to allege that *Latisse I-IV* are sham litigations, Akorn's conspiracy to monopolize claim (Count VII) should be dismissed as well.

**B. Count VIII: Akorn's Bare Allegations of Sham Litigation Cannot Support a Patent Misuse Claim**

The Federal Circuit has "characterized patent misuse as the patentee's act of impermissibly broaden[ing] the physical or temporal scope of the patent grant with anticompetitive effect." *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1328 (Fed. Cir. 2010) (internal quotation marks omitted). Akorn fails to plausibly allege any such broadening. Akorn's patent misuse claim is based solely upon Plaintiffs' enforcement of patents issued by the USPTO and presumed valid. But the Federal Circuit held that "[i]t is not patent misuse to bring suit to enforce patent rights not fraudulently obtained...." *C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998) (reversing a jury verdict finding patent misuse based on an incorrect jury instruction that patent misuse could be found if the patentee effectively engaged in sham litigation). There was no fraud, and Akorn alleges no such fraud; therefore Akorn's claim premised solely on sham litigation cannot amount to patent misuse as a matter of law. *See ESCO Corp. v. Cashman Equip. Co.*, 158 F. Supp. 3d 1051, 1071–72 (D. Nev. 2016) (granting 12(b)(6) dismissal of patent misuse claim: "[M]erely alleging that [plaintiffs] asserted the various patents-in-suit to unlawfully monopolize the market does not equate to patent misuse. A patent owner cannot be guilty of misuse simply for seeking to enforce his patent rights against infringement."); *cf. Pace Int'l, LLC v. Indus. Ventilation, Inc.*, No. 08-1822, 2009 WL 2460999, at \*1 (W.D. Wash. Aug. 6, 2009) (striking patent misuse defense: "[T]he Federal Circuit has determined that allegations of wrongful enforcement are insufficient to establish patent misuse . . .").

Additionally, Akorn's naked assertions that Plaintiffs expanded the scope of their patents

without *any* factual allegations fall short under *Twombly* and cannot save Akorn's claim. *See, e.g., Otsuka Pharm. Co. v. Torrent Pharm. Ltd.*, 118 F. Supp. 3d 646, 659 (D.N.J. 2015) (dismissing patent misuse claim "hinge[d] upon . . . allegedly bad faith conduct in pursuing [] 'baseless' patent infringement action" because it failed to plead how it "impermissibly broadened the physical or temporal scope of" the patents); *GoDaddy.com, LLC v. RPost Commc'ns Ltd.*, No. 14-126, 2014 WL 6908507, at \*5 (D. Ariz. Dec. 9, 2014) (dismissing patent misuse claim "[b]ecause GoDaddy has pled that RPost has acted in bad faith without pleading any facts that indicate an impermissible broadening of the Patent-in-Suit"). Akorn's patent misuse Counterclaim (Count VIII) accordingly fails and should be dismissed.<sup>10</sup>

#### **V. AKORN'S IDENTICAL ANTITRUST AND PATENT MISUSE DEFENSES ARE REDUNDANT AND FACIALLY INSUFFICIENT FOR THE SAME REASONS**

Akorn attempts to bypass pleading requirements by repackaging its Antitrust and Misuse Counterclaims as affirmative defenses. But Akorn's defenses again contain nothing more than "bare-bones conclusory allegations" that this Court should strike "to clean up the pleadings, streamline litigation, and avoid unnecessary forays into immaterial matters." *Sonos*, 2016 WL 4249493, at \*2 (striking patent misuse defense). Akorn's Antitrust and Patent Misuse Defenses are deficient under Rule 8 and should be stricken as redundant and facially insufficient for all of the same reasons that its identical Counterclaims fail. *See ESCO*, 158 F. Supp. 3d at 1072 (striking affirmative defense with counterclaim: "The assertions made under Defendants' patent misuse affirmative defense are similar to what is alleged under the counterclaim."); *Consumerinfo.com, Inc. v. Chang*, No. 09-3783, 2009 WL 10673208, at \*7 (C.D. Cal. Nov. 12, 2009) (same: "One

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<sup>10</sup> Even if the conduct underlying sham litigation could amount to patent misuse (which it does not), and notwithstanding the Federal Circuit's *C.R. Bard* decision, Akorn's claim would still fail for the same reason that Akorn does not plausibly allege that Plaintiffs engaged in any objectively baseless litigation.

Tech does not provide sufficient factual basis for its antitrust defense for the reasons that the Court finds that One Tech did not state a claim under its antitrust counterclaim.”); *see also Schwarz Pharma, Inc. v. Teva Pharms. USA, Inc.*, No. 01-4995, 2005 WL 4158850, at \*9 (D.N.J. Feb. 4, 2005) (denying as futile an accused infringer’s motion for leave to amend to assert patent misuse as an affirmative defense and counterclaim where a prior Federal Circuit ruling made clear that there was “no merit” to an improper Orange Book listing challenge).<sup>11</sup>

Additionally, courts find that “[w]hen an affirmative defense is unsupportable as a matter of law, it should be stricken in order to avoid unnecessary litigation on the question.” *FDIC v. Ornstein*, 73 F. Supp. 2d 277, 279–80 (E.D.N.Y. 1999); *see also Depomed*, 2017 WL 2804953, at \*9 (striking patent misuse defense because the asserting party did “not present any additional facts or theories that could plausibly support an affirmative defense”). As discussed above, Akorn’s sham litigation claims fail as a matter of law if Plaintiffs had a reasonable basis to file suit—which they did—and allegations of sham litigation cannot legally form the basis of patent misuse according to the Federal Circuit. *See supra* Section II.B. The Court should accordingly strike Akorn’s Antitrust and Misuse Defenses (Seventh, Eighth, Ninth) as well.

### **MOTION TO BIFURCATE AND STAY ARGUMENT**

Alternatively, the Court should exercise its discretion to bifurcate and stay Akorn’s Antitrust and Misuse Counterclaims (Counts IV-VIII) and Defenses (Seventh, Eighth, Ninth) until the validity of the ’270 patent is adjudicated. It is well-settled that this Court has the inherent authority to control its own docket, and the decision to bifurcate claims and stay discovery is within the district court’s discretion. *See Landis*, 299 U.S. at 254–55; *Warner Lambert Co. v. Purepac*

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<sup>11</sup> *See also PODS Enters., Inc. v. ABF Freight Sys., Inc.*, No. 11-84, 2011 WL 4948397, at \*6 (M.D. Fla. Oct. 17, 2011) (striking affirmative defense that was “premised on the same antitrust allegations as its antitrust counterclaims”).



*Pharm. Co.*, No. 00-02053, 2000 WL 34213890, at \*11 (D.N.J. Dec. 22, 2000). The Supreme Court also cautioned that “[p]rivate antitrust litigation can be enormously expensive.” *Twombly*, 550 U.S. at 573. Therefore, “Rule 8 . . . does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678–79 (2009).<sup>12</sup>

The Federal Circuit recognized over 30 years ago the “standard practice” to “separat[e] for trial patent issues and those raised in an antitrust counterclaim.” *Innotron*, 800 F.2d at 1084. Based upon this guidance, numerous courts, especially in the Third Circuit, have adhered to this “standard practice” of bifurcating antitrust counterclaims from underlying patent infringement claims, and staying discovery on them.<sup>13</sup> The same result is warranted here for Akorn’s Antitrust and Misuse Counterclaims along with its identical affirmative defenses. *See, e.g., Eurand Inc. v. Mylan Pharms. Inc.*, No. 08-889, 2009 WL 3172197, at \*2 (D. Del. Oct. 1, 2009) (bifurcating and staying antitrust and patent misuse counterclaims **and** related affirmative defense for the same reasons: “[A]ny economies derived from severing the antitrust issues from the case at bar would be minimized by failing to also sever the issues of patent misuse.”).<sup>14</sup>

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<sup>12</sup> *See also* Fed. R. Civ. P. 1 (“[Civil actions] should be construed, administered, and employed by the court and the parties to secure the just, speedy, and inexpensive determination of every action and proceeding.”).

<sup>13</sup> *See, e.g., Fresenius Kabi USA, LLC v. Fera Pharm., LLC*, No. 15-3654, 2017 WL 2213123, at \*5 (D.N.J. May 19, 2017) (bifurcating and staying discovery of defendant’s antitrust counterclaims); *Otsuka Pharm. Co. v. Apotex Corp.*, No. 14-8074, 2016 WL 6246801, at \*5 (D.N.J. Aug. 26, 2016) (same); *Torrent Pharm.*, 118 F. Supp. 3d at 659-60 (same); *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, No. 07-2762, 2009 WL 10678670, at \*1 (D.N.J. Apr. 9, 2009) (same); *Orthophoenix, LLC v. Dfine, Inc.*, No. 13-1003, 2015 WL 1938702, at \*1 (D. Del. Apr. 28, 2015) (same); *Masimo Corp. v. Philips Elecs. N. Am. Corp.*, No. 09-80, 2010 WL 925864, at \*1-4 (D. Del. Mar. 11, 2010) (same); *Abraxis Bioscience, Inc. v. Navinta LLC*, No. 07-1251, 2008 WL 2967034, at \*8 (D.N.J. July 31, 2008) (same); *Warner Lambert Co. v. Purepac Pharm. Co.*, No. 98-2749, 2000 WL 34213890, at \*11-13 (D.N.J. Dec. 22, 2000) (bifurcating patent claims from the unfair competition claims).

<sup>14</sup> *See also Masimo Corp. v. Philips Elecs. N. Am. Corp.*, No. 09-80, 2010 WL 1544423, at \*4 (D. Del. Apr. 19, 2010) (“Philips’ affirmative defense of patent misuse is bifurcated along with Philips’



**I. JUDICIAL EFFICIENCY FAVORS A STAY BECAUSE THE OUTCOME IN *LATISSE IV* COULD MOOT OR NARROW AKORN’S COUNTERCLAIMS**

Courts, including in this Circuit, recognize that the resolution of an underlying patent dispute can eliminate sham litigation, as well as assist in streamlining the case. *See, e.g., Torrent Pharm.*, 118 F. Supp. 3d at 659 (“Critically, resolution of the patent infringement issues may render [defendant’s] antitrust Counterclaim moot, thereby serving the interests of judicial economy.”); *Sandoz*, 2009 WL 10678670, at \*1 (“Because resolution of the underlying patent case may impact the issues raised in the Counterclaims, the Court finds that bifurcation would bring about certain efficiencies.”). This reasoning applies equally here.

The adjudication of Plaintiffs’ claim for infringement of the patent-in-suit has the potential to entirely moot Akorn’s Antitrust and Misuse Counterclaims. Akorn cites Plaintiffs’ patent infringement lawsuit, as well as prior lawsuits, as the sole “exclusionary conduct” in violation of Section 2 of the Sherman Act. Courts routinely recognize, however, that non-frivolous litigation cannot give rise to antitrust liability as a matter of law. *See supra* Section I.A. Instead, Akorn must prove sham litigation, which as detailed above, requires a showing that a lawsuit (or a significant number of lawsuits) was, at a minimum, objectively baseless at the time of filing. If Plaintiffs prevail in *Latisse IV*—or even raise credible arguments with a reasonable chance of prevailing—then there will be no basis for Akorn’s Antitrust and Misuse Counterclaims. Bifurcating and staying Akorn’s Antitrust and Misuse Counterclaims (and identical Defenses) while proceeding with Plaintiffs’ infringement claims would therefore aid the Court by deciding a predicate issue and streamlining this case.

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antitrust counterclaims. Discovery relating to patent misuse will be stayed.”); *Audio MPEG, Inc. v. Dell Inc.*, 254 F. Supp. 3d 798, 808 (E.D. Va. 2017) (“The Court finds that it is appropriate to bifurcate Dell’s patent misuse defense along with Dell’s antitrust claims because of the significant overlap in alleged facts and legal arguments.”).

## II. COSTLY AND BURDENSOME UNRELATED ANTITRUST DISCOVERY FAVORS BIFURCATION AND A STAY

A party alleging sham litigation must also show *all of the elements of a Section 2 antitrust claim* (in addition to showing that the lawsuit(s) were objectively baseless). In order to succeed, Akorn must ultimately prove that Plaintiffs had “(1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.” *United States v. Grinnell Corp.*, 384 U.S. 563, 570–71 (1966). In addition, a private plaintiff must also establish antitrust standing and damages.

There are numerous antitrust-specific issues that involve time-consuming factual inquiries completely unrelated to the patent infringement lawsuit. *See e.g., Orthophoenix*, 2015 WL 1938702, at \*1 (“[A]ntitrust counterclaim raises complex issues potentially requiring discovery well beyond what is relevant to patent infringement and invalidity.”). These antitrust issues include: (1) “relevant market” (*i.e.*, whether other products are “reasonably interchangeable” with LATISSE®), *United States v. E.I. DuPont de Nemours & Co.*, 351 U.S. 377, 395 (1956)); (2) “monopoly power” (*i.e.*, whether Plaintiffs have “the power to control prices or exclude competition,” *Id.* at 391); and (3) antitrust injury (*i.e.*, whether Akorn suffered “injury of the type the antitrust laws were intended to prevent,” *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)).

With respect to alleged antitrust injury and claimed treble damages, Plaintiffs will now be entitled to extensive discovery of Akorn—as well as third parties that Akorn has injected into its antitrust claims. Akorn alleges, for example, that Plaintiffs (1) “rais[ed] [Akorn’s] cost of doing business directly or indirectly;” (2) “forestall[ed], frustrate[ed] and prevent[ed] Akorn’s ability to compete in the relevant market;” (3) “frustrate[ed], discourag[ed], and forestall[ed] third-party

competitors from entering the relevant market;” and (4) “depriv[ed] consumers of the benefits of lower-priced generic competition.” Ans. and Counterclaims, ¶ 197. Plaintiffs will need to test the substance of each of these claims, including whether it is true (or not) that Plaintiffs delayed Akorn in selling its generic or whether (in fact) any alleged delay was due to Akorn’s own unpreparedness to launch. In fact, Akorn only received final FDA approval in October 2018—*more than four years* after the Federal Circuit invalidated the claims of the ’029 and ’404 patents in 2014. Ans. and Counterclaims, ¶ 25. Plaintiffs will thus need to probe into all of the reasons for Akorn’s inability to launch its generic, including potential manufacturing issues, supply issues, diverted resources, its failure to gain FDA approval, and other factors independent of Plaintiffs’ patents.<sup>15</sup> These antitrust-specific issues will require unrelated lengthy and expensive fact, expert, and third-party discovery that will undoubtedly consume the parties’ resources and tax the Court with discovery disputes.

The Supreme Court has explicitly warned against “forget[ting] that proceeding to antitrust discovery can be expensive.” *Twombly*, 550 U.S. at 558. Given that extensive and burdensome antitrust discovery could be—and is likely to be—mooted altogether, the Court should bifurcate and stay Akorn’s Antitrust and Misuse Counterclaims and Defenses. If not, “the parties will have

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<sup>15</sup> Following a five-day bench trial, in a 100+ page opinion, the Delaware Chancery Court recently found (and the Delaware Supreme Court affirmed) that Akorn had systematic compliance and quality issues with its pharmaceutical business, including intentionally manipulating data submitted to the FDA with respect to certain drugs, such as eye products. *See Akorn, Inc. v. Fresenius Kabi AG*, No. 18–0300, 2018 WL 4719347, at \*101 (Del. Ch. Oct. 1, 2018) (holding that Akorn’s conduct constituted a “material adverse event” enabling Fresenius to terminate its over \$4 billion proposed acquisition of Akorn), *aff’d*, No. 18–535, 2018 WL 6427137 (Del. Dec. 7, 2018). Given that Akorn acquired Hi-Tech in 2014—nearly four years before FDA approval was granted—it will be relevant whether Akorn’s misconduct and commercial problems extended to its proposed Latisse® generic, whether the same individuals were involved with this product, and whether Akorn’s behavior impacted its dealings with the FDA and ultimately delayed regulatory approval and the launch of this product.

no choice but to go forward with what undoubtedly will be enormously expensive discovery, perhaps to find that the expense has been wasted if [Plaintiffs] prevail[] in the infringement action[] or if the infringement action [is a] close, hard fought case[.]” *Mitsubishi Heavy Indus., Ltd. v. Gen. Elec. Co.*, 720 F. Supp. 2d 1061, 1069 (W.D. Ark. 2010); *see also Fresenius*, 2017 WL 2213123, at \*4 (“If [patents found valid], then all of the discovery and litigation on complex issues peculiar to the antitrust counterclaims, such as market definition, anticompetitive effect, and damages, ***will have been wasted.***”) (emphasis added).

### **III. ABSENT A STAY, PLAINTIFFS WILL BE PREJUDICED BECAUSE COMPLEX ANTITRUST AND PATENT ISSUES WILL CONFUSE A JURY**

Next, injecting extraneous antitrust issues into an already complicated patent infringement case will likely cause jury confusion. Plaintiffs’ infringement claim will require jurors to understand complex issues surrounding infringement and validity, as well as facts of molecular properties and compounds related to bimatoprost, prostaglandins, and methods for hair growth. District courts in this Circuit have recognized that “add[ing] antitrust issues to patent issues would pose a difficult task ***for even the most astute of juries.***” *Ricoh Co. v. Katun Corp.*, No. 03–2612, 2005 WL 6965048, at \*1 (D.N.J. July 14, 2005) (emphasis added); *see also Orthophoenix*, 2015 WL 1938702, at \*1 (“There is also a likelihood that, absent a stay, a trial of patent infringement, patent validity, and antitrust issues before the same jury may lead to jury confusion.”).

In addition, Akorn’s presentation of its Antitrust Counterclaims “may unfairly sway the jury against [Plaintiffs] who will be an accused monopolizer.” *Hunter Douglas, Inc. v. Comfortex Corp.*, 44 F. Supp. 2d 145, 154 (N.D.N.Y. 1999); *see also Masimo Corp.*, 2010 WL 925864, at \*2 (“Philips’ allegations of monopolization could bias the jury when it evaluates Masimo’s patent claims.”). Bifurcation and a stay of antitrust discovery is thus warranted to avoid the potential for not only jury confusion, but also unfair jury bias against Plaintiffs.

#### IV. AKORN WILL NOT BE PREJUDICED BY A STAY OF DISCOVERY

Finally, Akorn will not be prejudiced by a stay of its Antitrust Counterclaims given its own delay. If Akorn truly believed that Plaintiffs were committing antitrust violations by bringing *Latisse I-III*, it could have asserted these claims against Plaintiffs years ago, but chose not to do so. Having made the strategic decision to forego asserting those antitrust counterclaims in prior proceedings, Akorn now cannot claim to be prejudiced by a stay. *See Monsanto Co. v. E.I. du Pont De Nemours & Co.*, No. 09-0686, 2009 WL 3012584, at \*2 (E.D. Mo. Sept. 16, 2009) (granting a stay and finding no prejudice to the parties where “[they] could have brought many of these [antitrust] claims years ago, yet instead they waited until this litigation”). Finally, there will be no delay to Akorn given that Plaintiffs’ patent infringement suit will adjudicate a necessary (but not sufficient) predicate for proving its Antitrust and Misuse Counterclaims—the validity of the underlying patent in *Latisse IV*.

#### CONCLUSION

Retired circuit Judge Richard A. Posner (sitting by designation) remarked, “[t]o avoid turning every patent case into an antitrust case, some threshold of plausibility must be crossed at the outset before a patent antitrust case should be permitted to go into its inevitably costly and protracted discovery phase.” *Asahi Glass Co. v. Pentech Pharm. Inc.*, 289 F. Supp. 2d 986, 995 (N.D. Ill. 2003). This statement applies with great force here. Akorn’s sham litigation claims fail far short of plausibly alleging that any lawsuit was objectively baseless or frivolous given that Plaintiffs prevailed in the district court in one action, the district court rejected arguments that Allergan’s claims were objectively baseless in two other actions, and the most recent action is currently pending. Accordingly, Plaintiffs respectfully request that the Court dismiss these Counterclaims (Counts IV-VIII) and strike these Defenses (Seventh, Eighth, and Ninth) altogether. Alternatively, if the Court were to conclude that dismissal is not appropriate at this time, then

Akorn's Antitrust and Misuse Counterclaims and Defenses should be bifurcated and stayed pending resolution of Plaintiffs' patent infringement action.

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Respectfully submitted,

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